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ASX ANNOUNCEMENT
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BNC105 PHASE II RENAL CANCER TRIAL RESULTS

- **Results show BNC105 utility in patients with advanced disease**
- **Identified biomarkers which correlate with patient benefit (progression free survival at 6 months)**
- **Addition of BNC105 to Afinitor treatment delayed disease progression in patient subgroups identified on the basis of metastases, previous nephrectomy and Fuhrman tumour differentiation grade**
- **Primary endpoint showed a similar proportion of patients in both treatment arms free of progression at 6 months in the unselected patient population**

Bionomics Limited (ASX:BNO, ADR:BMICY) today announced the results of the DISRUPTOR-1 trial of BNC105 in patients with metastatic renal cancer.

“The DISRUPTOR-1 trial has been the first of its kind in testing the combination of an mTOR inhibitor with a vascular disrupting agent in renal cancer, with the prospect of adding a new dimension to the renal cancer treatment armamentarium,” said Dr Deborah Rathjen, Bionomics’ CEO & Managing Director.

“Significant progress has been made in validating BNC105 as an anti-cancer agent. Through patient subgroup analysis and association of biomarkers to treatment benefit, the data from this trial shows us the best way forward to maximising the utility of BNC105 for renal cancer patients, as well as how to best employ the drug in other cancer types.”

“DISRUPTOR-1 has produced a ground-breaking discovery of potential biomarkers that may allow pre-treatment selection of patients most likely to benefit from BNC105.”

“We are exploring partnership opportunities for BNC105 and expect to attract a depth of interest given the compelling data generated from this trial and the recent ovarian cancer trial data,” Dr Rathjen added.

Outline of the DISRUPTOR-1 trial

Bionomics conducted this randomised Phase II clinical trial in patients with metastatic renal cell cancer with 139 patients enrolled at sites across the US, Singapore and Australia.

The trial design targeted patients who had previously failed up to two tyrosine kinase inhibitor therapies, randomising them to either of two treatment arms: one receiving the standard of care renal cancer drug Afinitor and the other receiving both Afinitor and BNC105. Patients who were progressing or who were intolerant to Afinitor monotherapy, were allowed to receive BNC105 single agent treatment. Patients were treated until disease progression or until adverse effects prohibited further therapy.

Data from a total of 136 patients (69 in the BNC105 + Afinitor arm and 67 in the Afinitor-only arm) treated in this study were able to be analysed. The combination of BNC105 and Afinitor was safe and tolerable. The adverse event profile of the combination arm did not significantly differ from that of the Afinitor-only arm, and mirrored the known and expected toxicities of Afinitor.

BNC105 combination treatment benefited patients with more advanced disease

In relation to the primary endpoint, the proportion of patients free of progression at 6 months in the unselected patient population was similar between the two arms (23 patients in the BNC105 + Afinitor arm, vs 20 patients in the Afinitor-only arm, roughly 1/3 of the patients in each arm, p=0.6625). The median Progression Free Survival (PFS) in the unselected patient population was also similar between the study arms (4.7 months in the BNC105 + Afinitor arm vs 4.1 months in the Afinitor-only arm).

An analysis of patient subgroups indicated that a 3.8 month increase in PFS favouring the BNC105 + Afinitor combination over Afinitor-only monotherapy was observed in patients with liver metastases (6.6 months vs. 2.8 months) . Metastatic lesions to the liver adversely affect prognosis, with an average 5-year survival rate of approximately 30%.

Patients with a previous nephrectomy (kidney removal) also showed a trend to improved PFS with the BNC105 + Afinitor combination than with Afinitor alone (7.1 months vs 4.1 months) with a 3 month improvement in PFS.

PFS in the BNC105 + Afinitor arm was increased by approximately 50% (from 4.1 to 6.4 months) in patients with Furhman Grade 2 histological differentiation grade. Furhman grade, based on nuclear and nucleolar morphology, is an independent prognostic factor for survival.

Taken together these results indicate that future clinical trials of BNC105 in renal cell carcinoma should be enriched for these patient subgroups.

“Defining responder patient subgroups is very important. Several drugs are now available for renal cancer patients. The latest experience suggests that we need to be more targeted in matching up the right drug with the right patient subpopulation. This need is becoming clearly evident for a number of agents currently in use in the renal cancer setting,” commented Dr Thomas E Hutson.

Dr Hutson is Director, GU Oncology, Charles A Sammons Cancer Center, Baylor University Medical Center, and Professor of Medicine, at the Texas A&M HSC College of Medicine. Dr Hutson was the global Principal Investigator for the DISRUPTOR-1 clinical trial.

"It is very clear that not only do we need to match the right drug with the right patient subgroup but we also need biomarkers that will help guide our decision. One of the most exciting aspects of the DISRUPTOR-1 trial data is the identification of biomarkers that change in response to the BNC105 + Afinitor treatment. Most importantly, statistical significance was demonstrated for several of these biomarker changes associated with the disease progressing or not at 6 months in patients treated with the BNC105 + Afinitor combination," Dr Hutson added.

Biomarkers identified associated with PFS at 6 months

In the DISRUPTOR-1 trial plasma biomarkers previously associated with BNC105 activity were analysed and this was a pre-specified exploratory endpoint. Logistic regression analysis demonstrated that biomarker changes were associated with disease progression at 6 months, in a statistically significant manner. The p-values associated with these changes span the range of 0.0136 to 0.0348.

"The association of significant biomarker changes with an important parameter of disease control such as progression-free-survival is to the best of our knowledge demonstrated for the first time with this study in renal cell carcinoma patients," said Dr José Iglesias, Bionomics' Chief Medical Officer.

"BNC105 has the potential to change the way renal cancer is treated and the DISRUPTOR-1 trial has given us an insight on those patients who respond best to treatment. This is valuable information to incorporate in future clinical trial design and from the regulatory and reimbursement perspectives," Dr Iglesias added.

Determination of overall survival over a period of 5 years, overall response rate of the combination and PFS of BNC105 monotherapy following Afinitor treatment data are still pending.

Data collection and analysis on these parameters is continuing and will be reported as it becomes available in scientific presentations and publications.

Webcast details follow this announcement.

Further details of the trial are given in the Clinical Appendix that accompanies this announcement.

FOR FURTHER INFORMATION PLEASE CONTACT:

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BIONOMICS: WEBCAST WEDNESDAY 19 MARCH
9:30AM AEDT (VIC/NSW)
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Who Bionomics Limited (ASX: BNO) CEO and Managing Director Dr Deborah Rathjen, Chief Medical Officer Dr José Iglesias, Vice President Research & Development Dr Gabriel Kremmidiotis and Principal Investigator Dr Thomas Hutson

What Announcement on results of Phase II BNC105 renal cancer clinical trial with opportunity for questions

Clinical Appendix

Study Title: BNC105 in combination with Afinitor® (everolimus) or following everolimus alone for progressive metastatic clear cell renal cell carcinoma following prior tyrosine kinase inhibitors.

Study Design: This trial evaluated the combination of BNC105 and everolimus for the therapy of progressive clear cell renal cell carcinoma following prior treatment with tyrosine kinase inhibitor(s) (Arm A). Additionally, patients progressing on everolimus alone were offered BNC105, which provided an opportunity to evaluate the activity of monotherapy with BNC105 (Arm B). Patients were randomized 1:1 to either Arm A or Arm B of the study

Patients administered BNC105 were treated in repeating 21-day cycles, each cycle consisting of two doses administered one week apart (i.e., on Days 1 and 8). Everolimus was orally administered as a 10 mg tablet once a day. The trial was run under a U.S. FDA Investigational New Drug application.

Study Summary: The purpose of this study was to determine whether BNC105 in combination with/following everolimus is effective in the treatment of progressive metastatic renal cell carcinoma following prior tyrosine kinase inhibitors.

Endpoints:
PRIMARY

- Improvement in 6-month progression free survival (PFS) with the addition of BNC105 to everolimus.

SECONDARY
- Response rate with combination therapy compared to everolimus alone.
- PFS with BNC105 alone in patients progressing on everolimus.
- The adverse events of the everolimus and BNC105 when administered as a combination or sequential regimen.
- Overall survival.

EXPLORATORY
- To determine the correlation of PFS with biomarkers.

About Bionomics Limited
Bionomics (ASX: BNO) is biopharmaceutical company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, memory loss and pain. Its oncology approach includes cancer stem cell therapeutics as well as vascular disruption in solid tumours. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

Bionomics' discovery and development activities are driven by its four proprietary technology platforms: MultiCore®, a diversity orientated chemistry platform for the discovery of small molecule drugs; ionX® , a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system; Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels); and CSC Rx Discovery™, which identifies antibody and small molecule therapeutics that inhibit the growth of cancer stem cells. These platforms drive Bionomics' pipeline and underpin its established business strategy of securing partners for its key compounds. Bionomics partners include Merck & Co and Ironwood Pharmaceuticals.

www.bionomics.com.au

Factors Affecting Future Performance
This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this presentation that relate to prospective events or developments, including, without limitation, statements made regarding Bionomics' development candidates BNC105, IW-2143 (BNC210), BNC101 and BNC375, our acquisition of Eclipse Therapeutics and ability to develop products from their platform, its licensing deal with Ironwood Pharmaceuticals, drug discovery programs and pending patent applications are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements.

There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward-looking statements, including risks related to our available funds or existing funding arrangements, a downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, Ironwood's decisions to continue or not continue development of IW-2143, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Results of studies performed on competitors products may vary from those reported when tested in different settings.

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